

Are MSCs and/or exosomes affected (contaminated) by vaccinations?

Some customers or patients might harbor some concerns regarding vaccinations, are opposed to such, or hesitant about vaccines in general, or about COVID vaccines in particular. A recurring question is whether we screen our donors, or their umbilical cords as the source of our products, for vaccinations or vaccine residues. Here, we provide some general information on the topic.

With our birth tissue recovery partner under IRB, we are following donor screening requirements per regulatory law. The FDA requires donor screening and donor eligibility per FDA 21 CFR 1271: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1271.85>

During the COVID-19 pandemic, vaccines have been developed to help protect people from the virus. Pregnant women are at an increased risk of severe illness and complications from COVID-19, which can potentially impact the health of the unborn baby. As a result, many health authorities have recommended vaccination for pregnant women, as long as there are no contraindications.

Available data suggests that COVID-19 vaccines do not pose an increased risk to pregnant individuals or their unborn babies. In fact, some studies indicated that pregnant women who received a COVID-19 vaccine may pass antibodies to their babies, potentially providing some protection after birth.

So, there is some evidence suggesting that COVID-19 antibodies can be transferred from the mother to the unborn baby. This occurs via the placenta, providing the baby with some level of passive immunity against the virus. Studies have shown the presence of COVID-19 antibodies in umbilical cord blood and breast milk of vaccinated mothers, indicating that this transfer of antibodies is possible.

Regarding the transfer of mRNA fragments or other components of the vaccine, there is limited data available. The mRNA vaccines (such as the Pfizer-BioNTech and Moderna vaccines) work by introducing a small piece of genetic material that encodes the spike protein of the SARS-CoV-2 virus. The body's cells use this genetic material to produce the spike protein, which then stimulates an immune response. The mRNA is rapidly degraded in the body and is not expected to cross the placenta or be incorporated into the baby's DNA.

While our donors are not specifically screened for their vaccine status, the overall vaccine compliance in the United States is very high, and it can be assumed that the donors did receive one vaccine or another in their lifetime. However, any transfer or 'cross contamination' of vaccine fragments can be ruled out for our products.

Both our MSCs and exosomes are derived from the umbilical cord's Wharton's Jelly (a gelatinous connective tissue within the umbilical cord), *not* from the placenta. As antibodies are typically bloodborne, and we are not using umbilical cord blood, there will be no vaccine-derived antibodies found in our products.

Finally, in the process of culturing our MSCs and harvesting our exosomes we have several purification steps that exclude any and everything other than the desired MSCs or exosomes. Our products are also sent for unbiased third-party testing to confirm a perfectly 'clean', uncontaminated and uncorrupted product, as we are exceeding even the very strict quality requirements for medical grade products as defined by the FDA.